Atty. Docket No.: 29997/068

JOINT INVENTORS

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APPLICATION FOR UNITED STATES LETTERS PATENT

SPECIFICATION

TO ALL WHOM IT MAY CONCERN:

Be it known that We, **John Michael GREEN II**, citizen of the United States, residing at 152 Robertson Way, Lincoln Park, New Jersey, 07035, and **José Luis Moctezuma de la Barrera**, a citizen of Germany and Mexico, residing at Vordere Poche 11, 79111 Freiburg, Germany; and have invented a new and useful **"SYSTEM FOR DETERMINING A POSITION OF A POINT ON AN OBJECT"** of which the following is a specification.

SYSTEM FOR DETERMINING A POSITION OF A POINT ON AN OBJECT

BACKGROUND

1. Technical Field

[0001] This invention relates generally to surgical navigation systems. More particularly, this invention relates to a substrate removably attached to a user that assists the user in determining the position of a point on an anatomical structure within a patient.

2. Background Art

[0002] The use of surgical navigation systems for assisting surgeons during surgery is quite common. Some systems are used to determine points of interest on organs or bony structures. Determining the precise location of a point on these anatomical structures has proved difficult. One typical surgical technique is to use rigid pointer devices, such as the one described in U.S. Patent No. 5,617,857, with surgical navigation trackers attached thereto. These conventional systems, however, have numerous problems. Present systems suffer from pointer lift-off concerns, where the tip of the pointer that should correspond to the point desired to be located on the anatomical structure has moved away from the bony structure or organ when the location is determined. Other problems arise with conventional techniques when the anatomical structure is relatively inaccessible, especially to rigid pointers that cannot bend around obstructions within the patient to reach the anatomical structure. This is especially problematic with the increased use of smaller incisions for surgical procedures. Also of great importance is the wasted time surgeons must tolerate when switching from pointers to the other surgical tools needed to operate on the patient. The present invention provides a system for determining the global position of a point on an anatomical structure that does not suffer from the same lift-off, inaccessibility, or time wasting problems of conventional techniques.

SUMMARY OF THE INVENTION

[0003] One embodiment of the present invention is directed toward a system for determining a global position of an anatomical structure. The system includes a surgical

navigation system. The system also includes a substrate capable of being removably mounted to an outer surface of a user's body. A sensor is attached to the substrate that can be tracked by the surgical navigation system. A positional device is attached to the substrate. Further, a finger mounted structure capable of communicating with the positional device is provided. Lastly, a first circuit is provided for calculating a global position of a point on the anatomical structure by correlating a position of the sensor and a position of the finger mounted structure.

[0004] A further embodiment of the present invention is directed toward a system for determining a global position of an object. The system includes a navigation system. The system also includes a substrate capable of being removably mounted to an outer surface of a user's body. A sensor is attached to the substrate that can be tracked by the navigation system. Additionally, the system includes a positional device attached to the substrate. Further, a finger mounted structure capable of communicating with the positional device is provided. Lastly, a first circuit is provided for calculating a global position of a point on the object by correlating a position of the sensor and a position of the finger mounted structure.

[0005] Another embodiment of the present invention is directed toward a method for determining a position of a point on an anatomical structure using a surgical navigation system. The method includes the step of mounting a substrate in a removable manner to an outer surface of a user's body, the substrate having a positional device and a sensor that can be detected by the surgical navigation system. Another step includes disposing a finger mounted structure on a finger of the user capable of communicating with the positional device. Lastly, the method includes the steps of placing the finger mounted structure on the point of the anatomical structure to be determined and determining the position of the point.

[0006] A yet further embodiment of the present invention is directed toward a method for determining a position of a point on an object using a navigation system. The method includes the step of mounting a substrate in a removable manner to an outer surface of a user's body, the substrate having a positional device and a sensor that can be detected by the

navigation system. Another step includes disposing the finger mounted structure on a finger of the user capable of communicating with the positional device. Lastly, the method includes the steps of placing the finger mounted structure on the point of the object to be determined and determining the position of the point.

[0007] A further embodiment of the present invention is directed toward a method for determining a position of a point on an anatomical structure through a small incision opening using a surgical navigation system. The method includes the step of placing a finger mounted pointer having a rigid tip on a finger of a user. The finger mounted pointer is capable of communicating with an external positional device mounted in proximity to the incision opening, the external positional device being associated with a sensor that can be detected by the surgical navigation system. Another step includes manipulating the finger mounted pointer so that the rigid tip is in contact with the point to be determined. Lastly, the method includes the step of determining the position of the point.

[0008] Another embodiment of the present invention is directed toward an apparatus for determining a position of a point on an anatomical structure. The apparatus includes a substrate capable of being removably mounted to an outer surface of a user's body. The apparatus also includes a sensor and a positional device attached to the substrate. Lastly, the apparatus includes a finger mounted structure capable of communicating with the positional device adapted to be mounted on a finger of the user.

[0009] Other aspects and advantages of the present invention will become apparent upon consideration of the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] FIG. 1 is a top plan view of an embodiment of a substrate used with a finger mounted structure;

[0011] FIG. 2 is a top plan view of an embodiment similar to FIG. 1 with a finger mounted structure on a different finger;

[0012] FIG. 3 is a an isometric view of an embodiment of another substrate with a finger mounted structure;

[0013] FIG. 4 is a perspective view of an embodiment of the substrate and finger mounted structure similar to the one seen in FIG. 1;

[0014] FIG. 5 is a top plan view of a substrate and finger mounted structure similar to the one seen in FIG. 3;

[0015] FIG. 6 is a top plan view of an embodiment similar to the one seen in FIG. 1 that uses a fiber optic device; and

[0016] FIG. 7 is a top plan view of an embodiment similar to the one seen in FIG. 1 that uses a magnetic tracker.

DESCRIPTION OF THE PREFERRED EMBODIMENT(S)

[0017] The present invention is directed toward a system for determining a position of a point on an anatomical structure 100. The system includes a navigation system (also known as a "surgical navigation system") 102 and a substrate 104. The substrate 104 includes a sensor 106 for interacting with the navigation system and a positional device 108 for determining the position of the anatomical structure 100. The substrate 104 is removably mounted to an outer surface 110 of a user's body. The structure and functioning of the surgical navigation system 102, the sensor 106, and the positional device 108 are disclosed in U.S. Patent Application Serial No. _____, filed March 11, 2004 (the application is entitled "System for Determining a Position of an Object," and was filed the same day as the instant application, with an attorney docket No. 29997/064), the disclosure of which is herein incorporated by reference.

[0018] While the present invention has a variety of applications in many different fields, of particular importance are the embodiments that utilize the invention in surgical environments. The anatomical structure 100 will therefore typically be found in a patient's body. In a preferred embodiment of the present invention, the anatomical structure 100 is a bony structure. However, the anatomical structure 100 could also be an organ or any other structure found within the patient's body. It is also envisioned that embodiments of the

present invention may be used to determine positions of points on objects outside of surgical applications. Therefore, any of the embodiments hereinafter mentioned in respect to the anatomical structure 100 may also be used with bony structures, organs, other structures within a patient's body, or any other object a user desires to find the position of a point on.

[0019] The invention as embodied in FIG. 1 comprises two distinct sections. One of the sections is a finger mounted structure 140 disposed on a finger of the user. In one embodiment, the finger mounted structure 140 is disposed on the index finger of the user. In another embodiment, depicted in FIGS. 2 and 2a, the finger mounted structure 140 is disposed on the middle finger to allow for greater reach. The second section is the substrate 104. In the present embodiment, the substrate 104 comprises a glove 144 disposed on the hand and wrist of the user. In some embodiments, the glove 144 of FIG. 1 could completely extend over the hand and/or wrist of the user, allowing the finger mounted structure 140 to be attached or in contact with the substrate 104. Other embodiments vary the degree of hand and wrist coverage to suit the needs and comfort of the user. FIG. 3 shows yet another embodiment of the present invention that utilizes clasp-like structures 146 to mount the substrate 104 on the user's hand and wrist. Similar clasping techniques, Velcro bands, adhesive material, or any other mounting structure known to those skilled in the art could be used to attach the substrate 104 to the outer surface 110 of the user's body.

[0020] While the present embodiment utilizes a single uniform substrate 104 that extends over a portion of the hand and wrist of the user, other embodiments may utilize non-uniform substrates with multiple components. It is also envisioned that other embodiments may use single or multiple component substrates 104 that extend over other areas of the outer surface 110 of the user's body, such as the arm or shoulder. Indeed, the substrate 104 could take on numerous forms that provide for user comfort and mobility. For example, the user may wish to have the sensor 106 attached to a discrete portion of the substrate 104 on the shoulder or back of the user, while the positional device 108 is disposed on another discrete portion of the substrate 104 on the arm or hand of the user. It is even possible that the positional device 108 can be temporarily attached to the patient at a point near the incision. The precise manner or

number of elements that comprise the substrate 104 is variable depending on the user's needs and the environment.

[0021] The embodiment of the substrate 104 in FIG. 1 is constructed of a sufficiently flexible material so as not to greatly retard the movement of the user's hand. Those skilled in the art will know what materials can provide sufficient user maneuverability. While the present embodiment is constructed of a generally flexible material, other embodiments may use more rigid metallic or plastic composites to construct the substrate 104 with generally similar advantageous properties. FIG. 3 shows clasp-like structures 146 that could be comprised of more rigid materials, but still would allow for good mobility of the user's hand. The present embodiment also has the added advantage of allowing the user to have the substrate 104 removably attached to the outer surface 110 of the user's body during use. The advantage of such a system may be realized in a surgical environment where a surgeon may need to use a surgical tool and also find the position of a point on an anatomical structure 100. The unobtrusiveness of the present embodiment allows the surgeon to garner point positional data while simultaneously holding or using another surgical tool. The surgeon no longer has to free up a hand by putting down the surgical tool and wasting valuable time.

[0022] As noted above, the substrate 104 is removably mounted to the outer surface 110 of the user's body. In the embodiments depicted in FIGS. 1-3, the sensor 106 and the positional device 108 are disposed on a portion of the substrate 104 closer to the back of the user's hand than the palm of the user's hand. However, various other embodiments dispose the sensor 106 and the positional device 108 in different manners on the substrate 104. In all embodiments, the sensor 106 should be positioned to allow communication between itself and the surgical navigation system 102. The positional device 108 must also be oriented to allow communication with the surgical navigation system 102, or, must be allowed to communicate with the sensor 106. Those skilled in the art will know how to relay the information between the various components.

[0023] In all embodiments, the sensor 106 or the positional device 108 may be fixedly attached to the substrate 104, or be detachable from the substrate 104. It is also envisioned that all of the other components of the present system may be interchangeable to suit the user's needs. Differently sized substrates 104 may be provided to suit the variable sizes of the outer surface 110 of the user's body. Such variations may include differently sized gloves 144. The finger mounted structure 140 may also be of varying size to accommodate differences in user finger length and width.

[0024] As previously mentioned, embodiments of the present invention also include a finger mounted structure 140 disposed on the finger 142 of the user. In use, the finger mounted structure 140 is placed adjacent a point on the anatomical structure 100 to determine a position of the point. The finger mounted structure 140 is capable of communicating with the positional device 108. By manipulating the finger mounted structure 140 adjacent to the anatomical structure 100 such as depicted in FIG. 1, the position of the point on the anatomical structure 100 relative to the sensor 104 is determined. In some embodiments, the position of the finger mounted structure 140 that corresponds to the point on the anatomical structure 100 is a position of a tip 150 on the finger mounted structure 140. The tip 150 could be located adjacent to a tip of the user's finger, adjacent to a pad of the user's finger, or anywhere along the length of the finger mounted structure 140. The tip 150 may also protrude from the finger mounted structure 140, as may be seen in FIG. 2a, or be relatively flat against the finger mounted structure 140, as may be seen in FIG. 2. By concatenating the positional information of the point on the anatomical structure 100 from the positional device 108 and the position of the sensor 106, a global position for the point on the anatomical structure 100 is ascertained. The global position of the point may be displayed in numerous manners as known to those skilled in the art, including using a display monitor (not shown).

[0025] It is also envisioned that the anatomical structure 100 may be mapped using the present embodiment of the invention. The finger mounted structure 140 may be disposed in, or adjacent to, an anatomical structure 100 that is desired to be mapped. The user then manipulates his finger, and the corresponding finger mounted structure 140, along the area to

be mapped. If the positional device 108 has been activated, the positional device 108 will be able to accumulate data on the position of a plurality of points on the anatomical structure 100. These discrete positions of points, measured relative to the sensor 106, may be concatenated with the respective sensor positional information and compiled to create a cloud point map of the anatomical structure 100.

[0026] The finger mounted structure 140 is also flexible enough to enable the finger mounted structure 140 to reach a point on the anatomical structure 100 that is obstructed from view or hard to reach. In many instances, surgeons are required to determine the position of points on anatomical structures 100 that are obstructed by foreign and non-foreign material with the patient's body. Typical rigid pointers used to determine positional information are not adequate in such scenarios. The present embodiment of the invention allows for the user to manipulate his finger, along with the finger mounted structure 140, to gain access to obstructed or hard to reach positions. The present embodiments also allow tactile feedback to the user to make the user aware of when he is touching the desired point on the anatomical structure 100. In many instances, surgeons using conventional pointers have taken inaccurate positional data because they took positional information at a point not touching the anatomical structure 100. This problem is obviated by allowing the user to feel where the anatomical structure 100 is and thereafter activate the positional device 108 at the appropriate time.

[0027] It is envisioned that in some embodiments, whether the user is seeking an obstructed or unobstructed point on the anatomical structure, the user will be able to reach the point through an incision in the patient's body that has a length less than 10 centimeters. In a more preferred embodiment, the user can gain access to the point on the anatomical structure within the patient's body with an incision length less than 5 centimeters. In a most preferred embodiment, the user gains access to the point on the anatomical structure through an incision length within the range of about 2.5 centimeters to about 5 centimeters. While the present embodiments have application in a wide variety of situations, including trauma scenarios where incisions may not be necessary, the relatively small incision size benefits the

patient by offering a less invasive procedure. Indeed, the present embodiments may have great application in surgery involving the knees, hips, shoulders, elbows, or spine of a patient where the small incision size and relative flexibility of the finger mounted structure 140 are particularly advantageous.

[0028] In some embodiments of the present invention, as seen in FIG. 4, the finger mounted structure 140 comprises a finger mounted pointer 180. The finger mounted pointer includes a rigid tip 182, which is placed adjacent the point on the anatomical structure 100 that the user wishes to find the position of. In some embodiments, as seen in FIG. 5, the finger mounted pointer 180 includes a depressible tip 184 that depresses when pressure is applied to it. In either embodiment, the position of the finger mounted structure 140 that corresponds to the position of the anatomical structure could be the depressible tip 184 or the rigid pointer 182. Typically, adequate pressure to depress the depressible tip 184 will result when the user pushes the depressible tip 184 against the point on the anatomical structure 100 he wishes to find the position of. In some embodiments, the depressible tip 184 acts as a switch to activate the positional device 108 to determine the position of the point on the anatomical structure 100. When the depressible tip 184 is pressed against the anatomical structure 100, it could be configured to take single, multiple, or continuous point determinations, and could also be configured to turn off when un-depressed. It is also envisioned that a transducer 188, shown in phantom, may be provided within the depressible tip that will activate the positional device 108 when a certain pressure value is reached. The user or a computer program could define the pressure value and adjust the pressure tolerance in light of the particular anatomical structure to be located. Other embodiments may utilize switches located on the substrate 104 to activate the positional device 108. FIG. 3 shows the substrate 104 with a switch 186 located on various areas of the substrate 104. Other embodiments only have one switch 186 located on the substrate 104. The same switches 186, or switches disposed in similar areas on the substrates 104 as those shown in FIG. 3, may be used to activate the sensor 106 or the surgical navigation system 102 in yet other embodiments. The location of the switch 186 can either be on the back of the hand as shown in FIG. 3 or located in the palm of the hand so that the switch can be activated by another

finger on the same hand. The use of the switch 186 can ensure that the device is activated when the pointer 182 is in the proper position. Other embodiments envision a device that constantly supplies a stream of positional data whenever the positional device 108 is operational. The transducer 188 can cooperate with software to define the limit or value of pressure to be applied so as to assist in the accurate positioning of non-rigid internal anatomical structures such as organs.

[0029] FIG. 6 shows another embodiment of the present invention, which has the finger mounted structure 140 connected to the substrate 104 by at least one fiber 200. The substrate 104 includes a fiber optic device 202 and the sensor 106, wherein there is a known relationship between the fiber optic device 202 and the sensor 106. The fiber 200 includes at least one bending sensor. As such, the bending sensors allow the user to determine the position of a point on the finger mounted structure 140 and relay this information to the fiber optic device 202. The point is preferably on the rigid tip 182 of the finger mounted pointer 180 or the depressible tip 184. By manipulating the finger mounted structure 140 adjacent to an anatomical structure 100, such as depicted in FIGS. 1 and 5, the position of the point on the anatomical structure 100 relative to the sensor 106 is determined. By concatenating the positional information from the fiber optic device 202 and the sensor 106, a global position for the point on the anatomical structure 100 is ascertained.

[0030] It is also envisioned that the substrate 104 mounted in a removable fashion to the outer surface 110 of the user's body could be utilized in conjunction with a magnetic tracker 300. As may be seen in FIG. 7, an embodiment utilizing a magnetic tracker 300 could be used in a similar manner and incorporate similar structure as that discussed above in accordance with the fiber optic device 202. In the present embodiment, a magnetic tracker 300 is disposed on the on the substrate 104 and has a known relationship with the sensor 106. The finger mounted structure 140 contains a magnetic sensor 302, which is in communication with the magnetic tracker 300. The magnetic sensor 302 is preferably disposed on or near the rigid tip 182 of a finger mounted pointer 180 or on the depressible tip 184. In use, data from the magnetic sensor 302 corresponding to the position of the point on the anatomical structure

100 relative to the sensor 106 is relayed to the magnetic tracker 300. By concatenating the positional information of the sensor 106 and the magnetic tracker 300, a global position of the point on the anatomical structure 100 may be determined.

[0031] It is also envisioned that the present embodiments may have applications outside of the surgical field. A substrate 104 mounted to the outer surface 110 of a user's body could be used in a variety of situations. Indeed, it is envisioned that embodiments could be used in any situation that calls for the precise determination of the position of a point on an object.

[0032] Numerous modifications to the present invention will be apparent to those skilled in the art in view of the foregoing description. Accordingly, this description is to be construed as illustrative only and is presented for the purpose of enabling those skilled in the art to make and use the invention and to teach the best mode of carrying out same. The exclusive rights to all modifications which come within the scope of the appended claims are reserved.